The Systems House, Inc.

Notch View Office Park
1033 Route 46
Clifton, NJ 07013

Tel. (973) 777- 8050
Fax (973) 777- 3063

DSCSA Rollup Update for 2020

As many of you may be getting questions or concerns about your compliance, I wanted to reach and outline how the MDS system will help you address these challenges. As well as point out our suggested best business practices. While we do not enforce or force you to follow these rules, this document is intended more as a guide to allow you to decide internally how you might want to update your practices and systems.

Please note this is a combination of Information collected from various conferences and Industry Groups HDMA, NCPA, HIDA, FDA, etc. however since the FDA is the current enforcement agency in charge I have used their site as the model for compliance. For those with more specific needs this document may not suffice.

If you have any comments or questions please email support@tshinc.com

And we will reach out directly.

http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm427033.htm

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Step 1.

Report licensure (third-party logistics providers and wholesale distributors)

Start Date	Trading Partner(s)	Requirement
11/27/2014	Third-party logistics providers	Report licensure and other information to FDA
1/1/2015	Wholesale distributors	Report licensure and other information to FDA

To assist third-party logistics providers and wholesale distributors to comply with the new reporting requirements, FDA published a draft guidance, Drug Supply Chain Security Act Implementation: Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers (December 2014). The draft guidance outlines the information that should be submitted to FDA, the timing of the submissions, a preferred format for the submissions, and a preferred method for reporting using FDA's CDER Direct Electronic Submissions Portal. FDA posted a webinar that provides an overview of annual reporting requirements.

Please note that MDS Does not do this for you. Your company will have to go to the CDER Website and register assuming you will be selling Pharmaceuticals or any Tracked item. Please review the links above on what is involved. Based upon feedback from MDS Clients this was not a big project and should allow you to get registered relatively quickly.

Suggested best practices include using the Reporting and Tools on the Pharma License Menu to create and report to FDA and you may use the CDER website to verify your partners.

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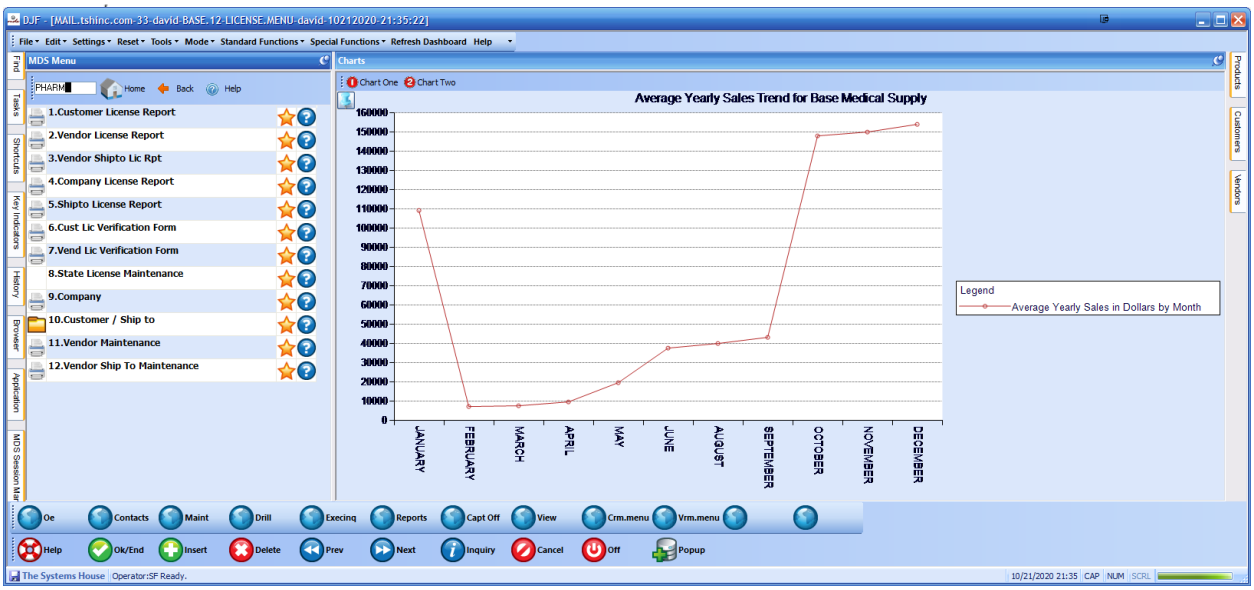

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Step 2.

Provide product tracing information (manufacturers, repackagers, wholesale distributors, and dispensers)

Start Date	Trading Partner(s)	Requirement
1/1/2015	• Manufacturers • Repackagers • Wholesale distributors	*Lot-level product tracing: provide transaction information, history, and statement*
7/1/2015	Dispensers (primarily pharmacies)	*Lot-level product tracing: provide transaction information, history, and statement*

To assist manufacturers, repackagers, wholesale distributors, and dispensers to comply with the new product tracing requirements, FDA has published a draft guidance for industry, DSCSA Standards for the Interoperable Exchange of Information for Tracing of Human, Finished Prescription Drugs: How to exchange product tracing information (November 2014).

- Accept ownership of product with applicable transaction information, transaction history, and transaction statements.
  - If your trading partner does not provide the proper transaction documentation, work with your trading partner to promptly get the proper documentation and to minimize disruption in the supply chain.

The MDS Pharma Module must be activated and configured to be able to track and pass this information (formerly known as a pedigree) we now refer to them as DSCSA Documents. And they include TI (Transaction Information), TS (Transaction Statements), and TH (Transaction History). You will enter the transaction history manually or can import it using the EDI 856 documents based upon the HDMA /HAD standards released, please note you will still need to inspect all goods and verify them, We will have the MDS QC and Audit Compliance Modules available to you to allow you to statistically sample your products rather than checking every item. Also, the requirement to have someone sign and authenticate each transaction has been replaced by the TS (transaction statement) on the form.

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Step 3.

Know how to handle suspect and illegitimate product (manufacturers, repackagers, wholesale distributors, and dispensers)

Start Date	Trading Partner(s)	Requirement
1/1/2015	• Manufacturers • Repackagers • Wholesale distributors • Dispensers (primarily pharmacies)	Establish systems for verification and handling of suspect or illegitimate product.

o assist manufacturers, repackagers, wholesale distributors, and dispensers to comply with the new verification requirements, FDA published the draft guidance for industry, Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification (June 2014). FDA posted a webinar that reviews how to identify suspect product and the process for notification.

- Establish systems to:
  - Quarantine and investigate *suspect product* to determine if it is illegitimate.
  - Notify FDA and immediate trading partners, if *illegitimate product* is found.

The MDS Pharma module includes our Excessive Product Usage System to assist you in setting up business rules to identify and stop any suspicious product. Additionally, you can use the MDS QC and Audit Compliance module to check on a statistical sampling of products receipts and invoices to verify that the items coming in and out are legitimate.

In the event of a suspicious item being identified the FDA requires you to fill out and submit a form (manually) *" Trading partners should follow the instructions on the Web page for accessing Form FDA 3911"* Using this form, trading partners should provide information about the person or entity initiating the notification, the product determined to be illegitimate or to pose a high risk of illegitimacy that is the subject of the notification to FDA, and a description of the circumstances surrounding the event that prompted the notification. Form FDA 3911 should be submitted by using the method provided in the form or on the Web page.

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Step 4.

Confirm authorized trading partners (manufacturers, repackagers, wholesale distributors, dispensers, and third-party logistics providers)

Start Date	Trading Partner(s)	Requirement
1/1/2015	• Manufacturers • Repackagers • Wholesale distributors • Dispensers • Third-party logistic providers	Must be authorized, as defined by the FD&C Act

- Check with your trading partner directly to confirm they are authorized, or
  - For manufacturers and repackagers, check FDA's drug establishment registration database for registration;
  - For wholesale distributors, third-party logistic providers and dispensers, you can check with your respective state authority to confirm licensure.

Note, third-party logistic providers are considered to be licensed under the DSCSA until the effective date of the third-party logistic provider licensing regulations issued by FDA, unless the third-party logistic provider is licensed by a state having a specific third-party logistic provider licensing program.

For more information about DSCSA implementation and new requirements to enhance drug distribution security, please visit FDA's Drug Supply Chain Security Act web page.

You will need to do this manually but the MDS system has been enhanced to allow you to store and report on any expiring licenses and codes.

There is a combination of state and federal licenses, but the goal is to consolidate them, and the FDA has fallen back on the DUNS number at this time. We shall see what the future holds but for now we have added fields for store and report on these licenses both for customer and vendors (all trading partners.) Additionally, the MDS Pharma System will warn and put orders on hold for license check failures allowing you to ensure compliance.

Updates for 2019

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2019 Brings with its Serialization Updates and Mandates The current enforcement date is November 2019

This is a basic overview of how to handle serial numbers today in the MDS System.

1. Prior to shipments coming in – we would expect trading partners (vendor/mfg.) to send in an EDI 856 doc with serials for each lot number , MDS will parse the EDI and during receipts you would Choose the "pending" pedigree info to attach to your receipts -much like we do for lots today.
2. Receiving would then open a percentage of boxes (optional QC and audit task created separately) to audit the receipt and verify the serials. Using Manual verification is just physically checking Items as they come in and making sure they match up to the EDI information.

Note as mentioned we don't see them sending this information, and not all manufacturers/vendors are setup via EDI as well. EPCIS data is supposed to be sent and MDS-Nx is prepared to parse and accept this data , but like an EDI file it will require some mapping and discussion, as some manufacturers will send you just the serials they shipped but many send you all the serials for the production run so that you can do your own verification of saleable returns.

In the event the EDI is not available, or the serials are not available via EDI, we have a new screen at receiving/button to allow you to train/create barcodes by Vendor

In the GS1 barcode screen we have added a new field for ScanID – if you are on the Scan Id field – we will parse the scanned barcode for
Identifiers - -https://www.gs1.org/standards/barcodes/application-identifiers?lang=en
Key ones are

01	Global Trade Item Number	n2+n14 GTIN
10	Batch or lot number	n2+an..20 BATCH/LOT
17	Expiration date (YYMMDD)	n2+n6 USE BY OR EXPIRY
21	Serial number	n2+an..20 SERIAL
240	Additional product identification assigned by the manufacturer	n3+an..30 ADDITIONAL ID

Each vendor may have different layouts for the data and or include different identifiers, the scanner you use will often add their own delimiters as well.
Because of this we need to know the scanners and what the delimiter used for your scanner is.

To make things simpler we are recommending you purchase Scan Avenger 3-in-1 Hand Scanners - Cordless, Rechargeable 1D and 2D Scan Gun for Inventory Management

Below is a and Example GS1 Data Matrix barcode.

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ScanAvenger Portable Wireless Bluetooth Barcode Scanner: 3-in-1 Hand Scanners - Cordless,...
~ 154
$58.97

This barcode contains 4 fields:

GTIN, or global trade identification number ,Lot or Batch number, Expiration Date, Serial Number One scan of this barcode returns all four fields which we then parse into 4 separate fields. The lot and serial number fields are variable in length. Variable length fields that fall within the middle of the barcode are appended with a group separator character. The Model Scanner Above Scan Avenger – can found on Amazon for under $60.

The original model we tested was # AS8862

https://www.amazon.com/gp/product/B07N8MG38F/ref=ppx_yo_dt_b_search_asin_title?ie=UTF8&psc=1

Out of the box this model will scan GS1 Data Matrix barcodes and provide the group separator character within the data.

Amazon is now shipping the new model # AS8880 , this model will scan GS1 Data Matrix barcodes but will **NOT** provide the group separator character. The scanner must be programmed by scanning the two images below.

Scan image #1 then image #2.

Image 1

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%%SpecCodeEF

Image 2

%%1D

Check the model number before you have the customer program the scanner. The model number can be found on a label next to the trigger.

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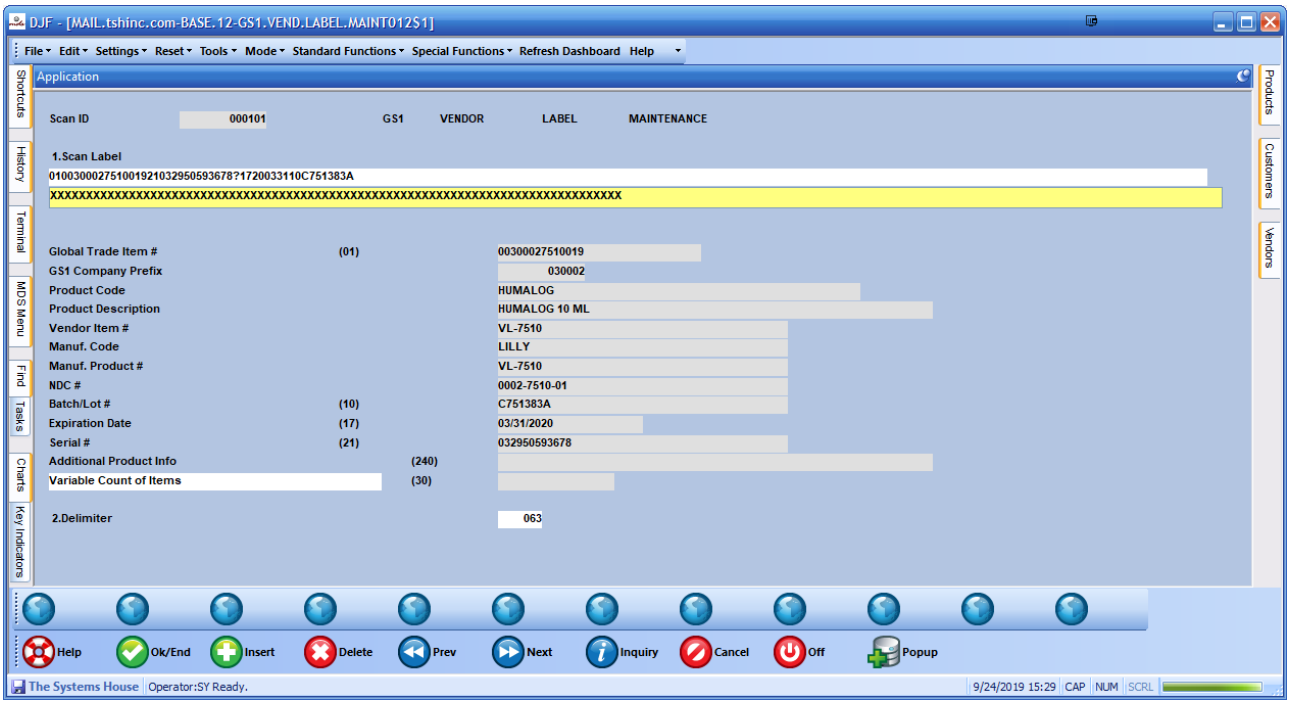
MDS Case 14722 includes the latest updates.



Note: If the manufacturer barcode is not sufficient you have the option to generate you own Data Matrix Barcodes using the MDS Nx system and a Zebra Printer– but this is not the recommended course of action , as you are not really generally the manufacturer.

3. Assuming you would need to scan each item – you can do so – but depending on customers' needs we will also offer an option for a starting/ending number based on scanning the GTIN Packaging code.

   In product master you would need to setup the correct packaging and GTIN numbers to allow us to scan the outer pack or case for a GTIN. And based on that quantity we can default the scan and assume the serials are sequential

4. Any inventory movement/adjustments etc. – will prompt for serial number or allow you to move all the serials for a lot
5. When shipping/verifying the product – verification will allow for scanning the item or location – and updating the Lot/Serial etc. based on them scanning.
6. Once items are shipping/invoiced – the EDI 856 and Pedigree Document will display the serial numbers and send them via EDI.

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Saleable returns requirement

What is a VRS and Do I Need to get one?

Updated 9/1/2020 – djf

Much like you must do today, as of November 2020 you are supposed to verify any product that is returned prior to selling it again. What has changed is that you now need to do this down to the serial number level , whereas before the lot number on the pedigree document (t3 info) and the pedigree itself were enough to verify this item was the one you sold.

One solution being offered is a **VRS - `Verification Router Service.`**

Below is a quick overview of how a VRS will work, it does not in any way require you to connect directly as most partners will have a web portal as well.

The manufacturers in theory must provide the information. However, should you wish to connect directly to the VRS so you do not have to retype or scan your serial numbers you can do so.

This would be treated like any other EDI transaction even If the format is slightly different. And is typically real time.

MDS-Nx supports the lightweight message standard for real time verification of the products. However currently (September 2020) – The responses are not standardized so you may need to review still manually what the status returned really means.

https://www.gs1.org/docs/standards/gs1_lightweight_verification_messaging_standard_v_1_0_2.pdf

The current best practice is to use the web portal to scan in your barcodes and verify them. Again, as VRS becomes more mainstream we will likely add them as EDI partners and Integrate the different providers, much like we do for EDI 856 documents today (electronic t3 info)

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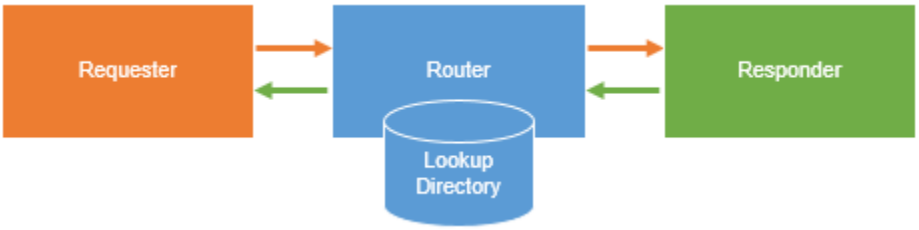
A Verification Router Service connects manufacturers and wholesalers

each one has a separate setup, and it would be a new EDI transaction for the verification etc.



The VRS model provides three basic service components:

Wholesalers use the requester service to create and submit a verification request and receive the response.

The router service uses its lookup directory to locate the product information and route the request to the correct source.

Manufacturers use the responder service to receive the verification request and respond to the requester.

Verification of Product Identifiers for pharmaceuticals Under the Drug Supply Chain Security Act (DSCSA) § 582(c)(4)(D), beginning November 27, 2019,

wholesaler distributors are required to verify the product identifier including Standardized Numerical 149 Identifier (SNI) of products returned to them before the returned products can be placed into inventory for resale. DSCSA defines verification as the process of "determining whether the product identifier affixed to or imprinted upon a package or homogeneous case corresponds to the [SNI] … assigned to the product by the manufacturer or the repackager…." [§ 581(28)]

"Verification" or "verify" means "determining whether the product identifier affixed to or imprinted upon on a package or homogeneous case corresponds to the [SNI] … assigned to the product by the manufacturer or the repackager…." [§ 581(28)]. A manufacturer who receives a verification request 156 from a repackager, wholesale distributor, or dispenser must respond to that request within 24 hours (or such other time the Food and Drug Administration (FDA) establishes) [§ 582(b)(4)(C)]. A repackager also has 24 hours to respond [§ 582(e)(4)(C)].

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For MDS-Nx Clients to simplify a vrs is just an electronic way of verifying the serial numbers are real.

Technically as part of dcsca - when you get a product in currently you are supposed to get a t3 doc (pedigree) - with the lot# on it. you are then supposed to verify the product is real with the manufacturer who is listed on the document. in november of this year (2019) they added the serial number to requirement, so you now must verify the serial number.

For Saleable Returns they have also required that all the items you get back as returned from your pharmacy/customers are verified.

Since you sold them - MDS would not allow you to take the return normally if the lot# does not match. And when you resell it - you can decide if you want to show the customer it was touched by another pharmacy who could have potentially swapped it for an older or different product. The T3 (pedigree) doc in MDS has the information you can choose what parameters you want and decide if this information shows to the next customer in your supply chain.

Having said that the VRS is not part of the law - it is just designed to make it easier and of course it will likely cost money on both sides. Most of the times much like the t3 info - the manufacturer picks up the cost and you just get the info delivered to you.

Current Solutions for Saleable Returns (Verification Router Service)

For saleable returns we can also verify using including EPICS (see lightweight messaging standard link above), VRS, Email/Phone, EPICS & VRS. If you prefer more manual approach, you can communicate directly with the manufacturer, provide the applicable information and once the verification is requested, the manufacturer is required to respond to these requests within 24 hours, again the web portal is likely the most common interaction. This should be like downloading a pedigree or t3 document today.

The issue of being able *to "verify"* a returned product using only the data stored in a distributor's system was discussed at a recent HDA Meeting and although it was not 100% confirmed legally, the consensus to be able to use stored data to verify a returned product was the following:

- Product MUST be purchased directly from the manufacturer/repackager
- Product elements "GTIN, Lot#, Serial #, Expiration Date" MUST be received electronically into the system, NO secondary service provider information is acceptable

What this would imply is only those distributors that are buying directly from the manufacturer/repackager can verify any returns using the data they are storing in their systems. Having said that this was a discussion, and no government entity has established this rule. However, we are providing as informational and Industry best practices.

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Grandfathered Product

There are currently non-serialized and serialized products in the market. And many of the product that are returns will have not have serialization as of November 2020. As a result of products with very long expiration dates, that were packaged prior to the November 2018 deadline, the FDA has implemented "Grandfathering" of such products.

However should you have a product that doesn't have a 2D barcode accompanied by the 4 data elements, this product will not meet the requirement by the DSCSA and after the November 2020 deadline, will no longer be able to be sold or received unless the product has been deemed as "Grandfathered". As it appears there will be many of these products still in the supply chain in November 2020. Again, there was no clear answer on what is considered a grandfathered product and as such your best course of action is to check with the FDA (The enforcement agency) for guidance.

Product Identification at the "Smallest Saleable Unit"

The DSCSA required that as of November 2018, Manufacturers and Repackagers apply serial numbers to what they deem to be the "smallest saleable unit". For some distributors, the smallest saleable unit is often the individual units within a case that are sold separately and may no longer be sold at this individual unit level.

Our best practice recommendation is that if you are a distributor that has in the past purchased by the case and sold individual units from that case to your clients, you must ensure that each unit level of product you are selling will have a serialized number in November 2020 . If not, you may have to re-think how you are going to sell this product. Or get permission from the manufacturer to relabel the product and or have them repackage on your behalf.

Alternately you can look at the MDS Manufacturing model for Drug Repackagers that will allow you to create a compliant drug repackaging operation.

As a reminder if you do not have the latest updates you will likely not have all these features so please make sure to update your MDS system as soon as possible to remain in compliance.